their derivatives, their analogs, their tautomeric forms, their stereoisomers, their polymorphs, their pharmaceutically acceptable solvates and pharmaceutical compositions containing them or their mixtures which may have agonist activity against PPARα and/or PPARγ, and optionally inhibit HMG CoA reductase, in addition to agonist activity against PPARα and/or PPARγ.

[0018] Another objective of the present invention is to provide pharmaceutically acceptable salts of β-aryl-α-oxysubstituted alkyl carboxylic acids of the formula (I) and their derivatives, their analogs, their tautomeric forms, their stereoisomers, their polymorphs, their pharmaceutically acceptable solvates and pharmaceutical compositions containing them or their mixtures having enhanced activities, without toxic effect or with reduced toxic effect.

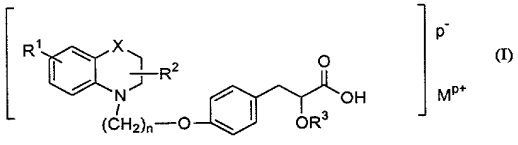
[0019] Yet another objective of the present invention is to provide pharmaceutically acceptable salts of the general formula (I) having better stability and physicochemical properties.

[0020] Yet another objective of the present invention is to provide a process for the preparation of pharmaceutically salts of β-aryl-α-oxysubstituted alkyl carboxylic acids and their derivatives of the formula (I) as defined above, their analogs, their tautomeric forms, their stereoisomers, their polymorphs, and their pharmaceutically acceptable solvates.

[0021] Still another objective of the present invention is to provide pharmaceutical compositions containing compounds of the general formula (I), their analogs, their derivatives, their tautomers, their stereoisomers, their polymorphs, their salts, solvates or their mixtures in combination with suitable carriers, solvents, diluents and other media normally employed in preparing such compositions.

Detailed Description of the Invention

[0022] The present invention relates to pharmaceutically acceptable salts having the general formula (I)



(I)

their derivatives, their analogs, their tautomeric forms, their stereoisomers, their polymorphs, wherein R^1 represents hydrogen, halogen atom such as fluorine, chlorine, bromine or iodine; hydroxy, nitro, cyano or lower alkyl group; R^2 represents hydrogen, lower alkyl or oxo group; X represents a heteroatom selected from oxygen or sulfur; R^3 represents hydrogen or lower alkyl group; n is an integer ranging from 1-4; M represents a counter ion (an anion which balances the ionic balance) or a moiety which forms a pharmaceutically acceptable salt; p is an integer ranging from 1 to 2.

[0023] The term lower alkyl represents linear or branched (C_1-C_6)alkyl group, such as methyl, ethyl, n-propyl, iso-propyl, n-butyl, iso-butyl, t-butyl, n-pentyl, iso-pentyl, hexyl and the like.

[0024] Suitable groups represented by M may be selected from glucamine, –methylglucamine, N-octylglucamine, dicyclohexylamine, methyl benzylamine, tris(hydroxymethyl)aminomethane (tromethamine), phenyl glycinol, lysine, aminoguanidine, or aminoguanidine hydrogen carbonate or metformin.

[0025] Suitable n is an integer ranging from 1 to 4, preferably n represents an integer 1 or 2.

[0026] Particularly useful compounds according to the present invention include:

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;